

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
TORRENT PHARMACEUTICALS LTD.,)
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Almirall, LLC (“Almirall”), by its undersigned attorneys, for its Complaint against Defendant Torrent Pharmaceuticals Ltd. (“Torrent”), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement brought under the United States Patent Act and the Hatch-Waxman Act, based upon Torrent’s submission of Abbreviated New Drug Application No. 214722 (the “Torrent ANDA”) to the United States Food and Drug Administration (“FDA”).

2. By the Torrent ANDA, Torrent seeks approval to market a generic dapsone gel, 7.5% drug product (the “ANDA Product”) prior to the expiration of United States Patent No. 9,517,219 (“the ’219 Patent”), which covers, *inter alia*, the use of Almirall’s ACZONE® Gel, 7.5% drug product, and which is listed accordingly in the FDA’s Orange Book.

PARTIES

3. Plaintiff Almirall is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 707 Eagleview Boulevard, Suite 200, Exton, Pennsylvania 19341.

4. Defendant Torrent is incorporated and existing under the laws of India, having a place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India.

JURISDICTION AND VENUE

5. This civil action for infringement of the '219 Patent arises under 35 U.S.C. § 271 and 21 U.S.C. § 355(j).

6. Original jurisdiction is vested in this Court over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201.

7. Upon information and belief, Torrent, directly or through its affiliates and agents, is present in, and conducts the business of and derives revenue from, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, in the State of Delaware.

8. Torrent has previously consented to and availed itself of the jurisdiction and venue of this District by, *inter alia*, asserting counterclaims and defenses in other civil actions initiated in this jurisdiction. *See, e.g., Bial – Portela & CA S.A., et al. v. Torrent Pharms. Ltd., et al.*, 20-cv-781, D.I. 15 (D. Del.); *Merck Sharp & Dohme Corp. v. Torrent Pharms. Ltd., et al.*, 19-cv-872, D.I. 18 (D. Del.); *Genentech, Inc. v. Torrent Pharms. Ltd., et al.*, 19-cv-324, D.I. 19 (D. Del.).

9. Torrent's affiliations with the State of Delaware are such as to render Torrent "at home" in this jurisdiction.

10. Upon information and belief, Torrent, directly or thought its affiliates and agents, participated, in the State of Delaware, in the preparation and/or filing of the Torrent ANDA, causing injury to Plaintiff Almirall.

11. In its business of developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products, Torrent has purposefully directed activities at residents of the State of Delaware.

12. If the FDA approves the Torrent ANDA prior to the expiration of the '219 Patent, upon information and belief, Torrent will market and sell the ANDA product throughout the United States, including in the State of Delaware, in violation of Almirall's rights in the patent.

13. This Court has personal jurisdiction over Torrent.

14. Almirall's assertion of personal jurisdiction is reasonable and fair.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

THE PATENT-IN-SUIT

16. On December 13, 2016, the United States Patent and Trademark Office issued the '219 Patent, entitled "Topical Dapsone and Dapsone/Adapalene Compositions and Methods for Use Thereof," a copy of which is attached as **Exhibit A** to this Complaint.

17. Plaintiff Almirall owns all rights, title, and interest in the '219 Patent.

ACZONE® GEL, 7.5%

18. Almirall is the holder of approved New Drug Application No. 207154 (the "ACZONE® NDA") for a topical drug product used to treat acne vulgaris, and containing, *inter alia*, 7.5% by weight of the active pharmaceutical ingredient, dapsone. The FDA granted approval of the ACZONE® NDA on February 24, 2016.

19. Almirall markets and sells the subject product of the ACZONE® NDA under the trade name ACZONE® Gel, 7.5%.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '219 Patent is listed in the FDA publication, "Approved Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to the ACZONE® NDA and ACZONE® Gel, 7.5%.

THE TORRENT ANDA

21. Torrent is the owner of the Torrent ANDA.

22. On information and belief, Torrent submitted, or caused to be submitted, the Torrent ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to market the ANDA Product as a generic version of ACZONE® Gel, 7.5%.

23. On information and belief, the Torrent ANDA refers to and relies upon the ACZONE® NDA and contains data that, according to Torrent, demonstrate the bioequivalence of the ANDA Product and ACZONE® Gel, 7.5%.

24. On or about August 26, 2020, Almirall received from Torrent a "Notice of Paragraph IV Certifications Re: Torrent Pharmaceuticals Limited's Dapsone Gel, 7.5%; U.S. Patent Nos. 9,161,926 and 9,517,219" (the "Notice Letter").

25. The Notice Letter provides notice that Torrent submitted to the FDA the Torrent ANDA, which included a certification by Torrent, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '219 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product prior to the patent's expiration ("Torrent's Paragraph IV Certification").

26. Torrent attached a memorandum (or "Detailed Statement") to its Notice Letter by which it alleged factual and legal bases for its Paragraph IV Certification. Torrent's Notice Letter provides allegations that the claims of the '219 Patent are invalid and/or will not be infringed by acts in relation to the ANDA Product as described in the Torrent ANDA.

27. The Notice Letter provides that Torrent seeks approval to market the ANDA Product before the '219 Patent expires.

CLAIM FOR INFRINGEMENT OF THE '219 PATENT

28. Almirall realleges and incorporates by reference Paragraphs 1 through 27 of this Complaint.

29. The Torrent ANDA is an application for FDA approval of Torrent to market the ANDA Product for, *inter alia*, use by physicians treating, and patients having, acne vulgaris.

30. Use of the ANDA Product as described in the Torrent ANDA is a method of treatment claimed in the '219 Patent.

31. The submission by Torrent to the FDA of the Torrent ANDA was an act of infringement of the claims of the '219 Patent.

32. The claims of the '219 Patent are not invalid.

33. The claims of the '219 Patent are infringed by acts in relation to the ANDA Product as described in the Torrent ANDA.

34. Approval of the Torrent ANDA prior to the expiration of the '219 Patent will injure Plaintiff Almirall as owner of the patent, holder of the ACZONE® NDA, and distributor and seller of ACZONE® Gel, 7.5% in the United States.

35. An actual case or controversy exists between Almirall and Torrent.

36. Almirall will be harmed substantially and irreparably if Torrent is not enjoined from infringing the '219 Patent.

37. Almirall has no adequate remedy at law.

38. Almirall is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Almirall prays for judgment in its favor and against Torrent and respectfully requests the following relief:

- (a) A judgment that Torrent has infringed one or more claims of the '219 Patent under 35 U.S.C. §271(e)(2);
- (b) An order, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any approval of the Torrent ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)), shall not be earlier than the expiration of the '219 Patent, including any extensions, adjustments, and exclusivities;
- (c) A grant, pursuant to 35 U.S.C. § 271(e)(4)(B), of an injunction against Torrent, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, preventing the commercial manufacture, use, offer to sell, or sale of the ANDA Product within the United States, or the importation the ANDA Product into the United States, prior to the expiration of the '219 Patent, including any extensions, adjustments, and exclusivities;
- (d) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the ANDA Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;
- (e) To the extent that Torrent has committed any acts with respect to the claimed subject-matter in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;
- (f) Attorneys' fees in this action, as an exceptional case pursuant to 35 U.S.C. § 285;

- (g) Costs and expenses in this action; and
- (h) Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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